SECTION 5
510(k) SUMMARY

510(k) Notification K 110541

GENERAL INFORMATION

Applicant:

Figure 8 Surgical, Inc.
890A Santa Cruz Avenue
Menlo Park, CA 94025
U.S.A.
Phone: 304-777-4677
Fax: 304-777-4679

Contact Person:

Kit Cariquitan
Vice President, Regulatory Affairs
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089-1330
U.S.A.
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Email: kitc@experiengroup.com

Date Prepared: February 24, 2011

DEVICE INFORMATION

Classification:

21 CFR§888.3010, Class II

Product Code:

JDQ

Trade Name:

Figure 8 Sternotomy Closure Device

Generic/Common Name:

Bone Fixation Cerclage

SECTION 5
510(k) SUMMARY

PREDICATE DEVICE

Ethicon Surgical Stainless Steel Suture (K931271)

INTENDED USE

The Figure 8 Sternotomy Closure Device is indicated for use in sternal closure procedures.

PRODUCT DESCRIPTION

The Figure 8 Sternotomy Closure Device ("Figure 8 SCD") is a permanent, medical grade 316L stainless steel implant intended for use in sternal closure following median sternotomy.

SUBSTANTIAL EQUIVALENCE

The indications for use for the Figure 8 SCD are substantially equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Figure 8 SCD is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the Figure 8 SCD to support a determination of substantial equivalence to the predicate device, including:

- Simulated Use Testing
- Functional Verification Testing

SUMMARY

The Figure 8 SCD is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Figure 8 Surgical, Inc.
% Mr. Kit Cariquitan
Regulatory Consultant
890A Santa Cruz Avenue
Menlo Park, California 94025

JUL - 6 2011

Re: K110541
Trade/Device Name: Figure 8 Sternotomy Closure Device
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: June 22, 2011
Received: June 23, 2011

Dear Mr. Cariquitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110541

Device Name: Figure 8 Sternotomy Closure Device

Indications For Use:

The Figure 8 Sternotomy Closure Device is indicated for use in sternal closure procedures.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110541